IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| MERCK & CO., INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | C.A. No. 06-230 (GMS) |
| APOTEX, INC., | ) | |
| Defendant. | ) | |

Mary B. Graham, Esquire, and James W. Parrett, Jr., Esquire, of MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware, and John DeQ. Briggs, Esquire, John F. Lynch, Esquire, Kenneth W. Donnelly, Esquire, Aaron Myers, Esquire, of HOWREY LLP, Washington, D.C., and Nicholas G. Barzoukas, Esquire, Suzy S. Harbison, Esquire, Jason C. Abair, Esquire, of WEIL, GOTSHAL & MANGES, Houston, Texas, and Paul D. Matukaitis, Edward W. Murray, Gerard M. Devlin, of MERCK & CO., INC. Attorneys for Plaintiff.

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**OPINION**

May 21, 2007
Wilmington, Delaware

**SLEET, District Judge.**

## I. INTRODUCTION

The plaintiff Merck & Co., Inc. ("Merck") filed suit against the defendant Apotex, Inc. ("Apotex") in the above-captioned matter, alleging that Apotex committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A). Merck moves to dismiss its complaint for lack of subject matter jurisdiction because, since filing suit, it has given Apotex a comprehensive covenant not to sue, which removed the controversy between the parties. For the reasons that follow, Merck's motion is granted.

## II. SUMMARY OF STATUTORY FRAMEWORK

The provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments") govern the generic drug approval process.[1] The Food and Drug Administration ("FDA" or "Agency"), provides the following summary explanation of the Act's statutory provisions, at http://www.fda.gov/cder/about/smallbiz/generic_exclusivity.htm, which the court incorporates in pertinent part:

The Hatch-Waxman Amendments are intended to balance two important public policy goals. First, drug manufacturers need meaningful market protection incentives to encourage the development of valuable new drugs. Second, once the statutory patent protection and marketing exclusivity for these new drugs has expired, the public benefits from the rapid availability of lower priced generic versions of the innovator drug.

[1] The Hatch-Waxman Amendments were modified by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pub. L. No. 108-173, § 1101(a)(2)(A)(ii), 117 Stat. 2066 (amended 2003). Herein, all references to the Hatch-Waxman Amendments and its regulatory framework include the scope of the provisions as later modified.

The Hatch-Waxman Amendments amended the Federal Food, Drug, and Cosmetic ("FD&C") Act and created section 505(j). Section 505(j) established the abbreviated new drug application ("ANDA") approval process, which permits generic versions of previously approved innovator drugs to be approved without submission of a full new drug application ("NDA"). An ANDA refers to a previously approved new drug application (the "listed drug") and relies upon the Agency's finding of safety and effectiveness for that drug product. The timing of an ANDA approval depends in part on patent protections for the innovator drug. Innovator drug applicants must include in an NDA information about patents for the drug product that is the subject of the NDA. The FDA publishes patent information on approved drug products in the Agency's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." The FD&C Act requires that an ANDA contain a certification for each patent listed in the Orange Book for the innovator drug. This certification must state one of the following: (i) that the required patent information relating to such patent has not been filed; (ii) that such patent has expired; (iii) that the patent will expire on a particular date; or (iv) that such patent is invalid or will not be infringed by the drug, for which approval is being sought.

A certification under paragraph I or II permits the ANDA to be approved immediately, if it is otherwise eligible. A certification under paragraph III indicates that the ANDA may be approved on the patent expiration date. A paragraph IV certification begins a process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent. The ANDA applicant who files a paragraph IV certification to a listed patent must notify the patent owner and the NDA holder for the listed drug that it has filed an ANDA containing a patent challenge. The notice

must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed. The submission of an ANDA for a drug product claimed in a patent is an infringing act if the generic product is intended to be marketed before expiration of the patent, and therefore, the ANDA applicant who submits an application containing a paragraph IV certification may be sued for patent infringement. If the NDA sponsor or patent owner files a patent infringement suit against the ANDA applicant within 45 days of the receipt of notice, the FDA may not give final approval to the ANDA for at least 30 months from the date of the notice. This 30-month stay will apply unless the court reaches a decision earlier in the patent infringement case, or otherwise orders a longer or shorter period for the stay.

The statute provides an incentive of 180 days of market exclusivity to the "first" generic applicant who challenges a listed patent by filing a paragraph IV certification and running the risk of having to defend a patent infringement suit. The statute provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the patent invalid, unenforceable or not infringed, whichever is first. These two events—first commercial marketing and a court decision favorable to the generic—are often called "triggering" events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

In some circumstances, an applicant who obtains 180-day exclusivity may be the sole marketer of a generic competitor to the innovator product for 180 days. But 180-day exclusivity can begin to run, with a court decision, even before an applicant has received approval for its ANDA. In that case, some, or all, of the 180-day period could expire without the ANDA applicant marketing its generic drug. Conversely, if there is no court decision and the first

applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period. Approval of an ANDA has no effect on exclusivity, except if the sponsor begins to market the approved generic drug. Until an eligible ANDA applicant's 180-day exclusivity period has expired, the FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the sponsors are willing to immediately begin marketing. Therefore, an ANDA applicant who is eligible for exclusivity is often in the position to delay all generic competition for the innovator product.

## III. BACKGROUND

Merck is the owner of nine patents listed in the Orange Book for the drug alendronate sodium, which Merck markets and sells under the trademark Fosamax.[2] On February 24, 2006, Apotex sent Merck a letter informing Merck that Apotex filed ANDA No. 077-982, seeking approval from the FDA to market a generic version of Merck's Fosomax tablets. Apotex certified in its ANDA submission that certain Merck patents were invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Apotex's generic version. Apotex was not the first generic filer to challenge Merck's patents on the Fosamax drug.

In the absence of any further information than what Apotex provided in its February 2006 letter, on April 7, 2006, Merck filed this action to protect its rights under the Hatch-Waxman Act. Apotex counterclaimed for a declaratory judgment of invalidity and noninfringement of the nine patents at issue. In August 2006, after receiving more detailed information from Apotex

[2] The patents listed in Merck's NDA, which are the patents-in-suit, are U.S. Patent Nos. 5,358,941; 5,681,590; 5,849,726; 6,008,207; 6,090,410; 6,194,004; 5,994,329; 6,015,801; and 6,225,294.

regarding its generic version of Fosamax, Merck granted Apotex a comprehensive covenant not to sue.

## IV. LEGAL STANDARD

The exercise of judicial power under Article III of the United States Constitution requires the existence of a case or controversy. The Declaratory Judgment Act "requires an actual controversy between the parties before a federal court may exercise jurisdiction over an action for a declaratory judgment." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996). The actual controversy requirement is met when, "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issue of a declaratory judgment." *Id.* (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 213 U.S. 270, 273 (1941)). When an actual controversy does exist sufficient to warrant subject matter jurisdiction, however, "the district court is not required to exercise declaratory judgment jurisdiction, but has discretion to decline that jurisdiction." *EMC Corp.*, 89 F.3d at 810.

## V. DISCUSSION

Merck argues that, as a result of its covenant not to sue Apotex on the asserted patents, this action is moot and the court lacks subject matter jurisdiction over the purported controversy. Conversely, Apotex asks that the court deny Merck's motion for the following reasons: (1) a dismissal without a finding of invalidity and/or noninfringement would operate to deny Apotex "its right to compete with Merck for want of a 'triggering event'" and that Apotex would be injured by delayed entry into the market; (2) the court should not sanction Merck's "manipulating the court's jurisdiction" by filing a patent infringement suit, later presenting a covenant not to sue, and

then attempting to dismiss Apotex's counterclaims for lack of subject matter jurisdiction; and (3) the court has subject matter jurisdiction because this case satisfies the Supreme Court's test for determining an actual case or controversy. (D.I. 19 at 2.)

**Existence of an Actual Case or Controversy**

In *Teva v. Novartis*, the Court of Appeals for the Federal Circuit ("Federal Circuit") acknowledged that the Supreme Court, in *MedImmune v. Genentech*, 127 S. Ct. 764 (2007), disagreed with the Federal Circuit's "reasonable apprehension of suit" test, and refocused the declaratory judgment jurisprudence on earlier Supreme Court precedent. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007). Thus, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune v. Genentech*, 127 S. Ct. at 771 (citing *Md. Cas. Co.*, 312 U.S. at 273). In support of its argument that an actual case or controversy exists in this case, Apotex points to the Federal Circuit's observation in *Teva v. Novartis*:

> A justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents.

482 F.3d at 1344. The court agrees with the Federal Circuit's observation about what ***establishes*** a justiciable declaratory judgment controversy in the Hatch-Waxman context. Further, the court recognizes that, when filed, this case also presented a justiciable controversy. A significant

distinction between the scenario in *Teva v. Novartis* and the case here is that Novartis had declined to give Teva a covenant not to sue. Here, after the case was filed, and Merck received further information upon which it could evaluate the infringement action, Merck presented Apotex with a comprehensive covenant not to sue. The actual controversy must be in existence at all stages of the litigation and cannot merely be present at the filing of the complaint. *Super Sack v. Chase*, 57 F.3d 1054, 1058 (Fed. Cir. 1995).

Article III standing requires "[a] plaintiff [to] allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *Allen v. Wright*, 468 U.S. 737, 751 (1984). Here, having received a covenant not to sue, Apotex does not and cannot allege "*unlawful* conduct" attributable to Merck in connection with its declaratory judgment claim. Further, Apotex's articulated injury—delayed entry to the market—is not fairly traceable to Merck. There is no evidence to conclude that Apotex's delayed entry into the market is any different than what it would have been had Merck never sued it. Thus, Apotex's advancement of this case against Merck becomes merely a means to an end, where the desired "end" is a triggering event but the means to that end, the litigation itself, is not sanctioned under the current legal framework. To proceed to a substantive "court decision" on the merits of Apotex's claims of noninfringement or invalidity would amount to an impermissible advisory opinion. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975) (holding that courts may not render advisory opinions or decide questions that do not affect the rights of the parties to the case).

Merck's covenant not to sue removes any cause for concern that Apotex could be held liable for infringement of the patents in suit. *See Super Sack*, 57 F.3d at 1059. Moreover, "'[i]t is well-established that a trial court may be divested or deprived of subject matter jurisdiction over a particular patent claim if the patentee covenants not to assert an infringement claim against a

putative infringer.'" *Crossbow Tech., Inc. v. YH Tech., Inc., No.* C 03-04360, 2007 WL 174422, at *2 (N.D. Cal. Jan. 22, 2007) (quoting *Eli Lilly & Co. v. Zenith Goldline Pharms.*, 101 F. Supp. 2d 1139, 1142 (S.D. Ind. 2000)). Federal Rule of Civil Procedure 12(h)(3) states "[*w*]*henever* it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter, the court shall dismiss the action." Accordingly, the court must dismiss this action for lack of subject matter jurisdiction.[3]

**Manipulation of Court Jurisdiction**

Notwithstanding the body of law that mandates dismissal, the court is sensitive to Apotex's argument that Merck is manipulating the court's jurisdiction. Indeed, the court must guard its jurisdiction jealously. Apotex highlights an interesting yet troublesome practice that has emerged from the interplay of the Hatch-Waxman regulatory scheme, covenants not to sue, subject-matter jurisdiction, and the typical time cycle of a patent litigation. This lawsuit exposes the ability of pioneer drug companies to potentially hold generics at bay by suing them, as they are authorized to do when a paragraph IV certification is made in an ANDA, and then granting a covenant not to sue, which divests the court of subject-matter jurisdiction. In this way, district courts can be viewed as unwitting agents in a pioneer drug company's ability to defer competition for as long as possible. As unfortunate as it may be for Apotex, this is the framework that the Hatch-Waxman Act

[3] Apotex also contends that the collateral consequences doctrine permits the court to retain jurisdiction. The court has considered the parties' arguments and finds Apotex's position to be without merit.

created.[4] The legislative history suggests that, in fact, Congress contemplated the use of covenants not to sue as a means of resolving any controversy created by the filing of an ANDA:

> The provision [a "civil action to obtain patent certainty"] . . . is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. ***We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe***.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of Senate HELP committee) (emphasis added)).

ANDA litigation reaches the federal courts through specialized legislation enacted by Congress, perhaps without the prescience of the maze it would be creating, and the ingenuity of motivated business persons and lawyers to capitalize on its imperfections. These cases represent the intersecting roles of all three branches of government and the pharmaceutical industry: the court's interest in interpreting the existing law so that it can provide justice and equity to injured parties; congressional interest in making laws that will encourage research and development, as well as to speed entry of generic drugs into the market; a regulatory agency's interest in advancing

[4] The court is also troubled by the practical realities of a scheme, which in effect, if left as is, enmeshes the district courts in unnecessary, and in this court's opinion, improper involvement in business competition. This cycle not only contributes to court congestion but it wastes the court's valuable time and limited resources by conducting the business it must for these cases, until it reaches the merits of such contested motions to dismiss. The time-triggered provisions of the statute unrealistically presuppose the time in which the district courts are to manage their cases. While the court endeavors to be efficient and expeditious in resolving the matters pending before it, time proscriptions such as those that Congress has assumed in the Hatch-Waxman provisions, and those upon which the litigants press the court, are idealistic at best and unfeasible in practice. The joint effort of the branches of government to balance the interests of consumers with those of innovator and generic drug companies should not be so tunnel-visioned as to facilitate litigants in their attempts to catapult ANDA litigation as a priority in the district courts.

the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and the pharmaceutical industry's interest in protecting its bottom line. This court is without the power, however, to ameliorate the problems that have emerged from this interplay.

Apotex argues that the Federal Circuit, in *Teva v. Novartis*, recognized that a patentee's actions of only suing on one of its patents frustrated the central purpose behind Hatch-Waxman, and that this court should similarly recognize the gamesmanship behind suing, covenanting not to sue, and moving to dismiss without a decision on the merits. In finding a justiciable controversy in *Teva v. Novartis*, however, the Federal Circuit found frustration of the Hatch-Waxman Act's purpose to be just one of numerous circumstances, in the "totality of circumstances" analysis, that warranted a finding of an actual controversy. 482 F.3d at 1344. Moreover, in the past, both innovator and generic companies have been accused of "gaming" the Hatch-Waxman regulatory regime to their respective benefit.[5] Congress responded through legislation. *See* 149 Cong. Rec. S15882-03, S15885 (Nov. 25, 2003) ("[I]n recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the [ ] Act . . . will stop these abuses.") (remarks of Sen. Kennedy, ranking member of the Senate HELP committee regarding the 'civil action to obtain patent certainty' provision under 21 U.S.C. § 355(j)(5)(C)). Likewise, if it is the view of Congress that pharmaceutical companies are abusing the Act in the way that Apotex complains here, Congress can reform the Hatch-Waxman Amendments as it deems necessary.

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[5] The Federal Trade Commission issued studies in 2002 and 2003 that examined and commented on the conduct of drug companies in the generic drug approval process. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, (2003), available at http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

**Right to Competition – Antitrust Claim**

Apotex's argument that a dismissal without a finding of invalidity or noninfringement would operate to deny Apotex "its right to compete with Merck for want of a 'triggering event'" coincides with its proposed antitrust counterclaim presented in its motion to amend. As such, the court will address this argument and Apotex's motion together.

Recognizing that motions to amend shall be granted freely under Federal Rule of Civil Procedure 15(a), the court has discretion to deny leave to amend when there is undue delay, bad faith, dilatory motive or undue prejudice to the opposing party, or when the amendment would be futile. *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997). In assessing futility, the court applies the same standard of legal sufficiency as applies under Rule 12(b)(6). *Id.* Thus, the court looks to whether Apotex's antitrust claim, if allowed, would survive a motion to dismiss.

The Supreme Court has outlined the factors that courts should consider when determining whether a party has standing to bring a private action under the antitrust laws: (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d

Cir. 1998) (citing *Associated Gen. Contractors of California v. California State Council of Carpenters,* 459 U.S. 519, 537-45 (1983)).

Apotex argues, both in its opposition to Merck's motion to dismiss and in Apotex's motion to amend, that if the court grants Merck's motion to dismiss, the 30-month stay on Apotex's ANDA application will not be terminated, the 180-day exclusivity period will not be triggered, and Apotex, as well as the other secondary generic applicants, will be prevented from entering the generic market until 180 days after the first generic applicant enters the market. With these consequences in mind, Apotex asserts that Merck's actions of filing suit, covenanting not to sue, and moving to dismiss for lack of subject matter jurisdiction, are an unlawfully anticompetitive and monopolistic scheme to delay entry by Apotex and other generic filers into the market for generic alendronate sodium.

One material aspect of this discussion is whether the FDA's 30-month stay on Apotex's ANDA will terminate upon the court's dismissal of the action. The 30-month stay was introduced to give the generic applicant and NDA holder the opportunity to resolve patent issues prior to commercial marketing. Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf, at 39. 21 U.S.C. § 355(j)(5)(B)(iii)(2003) provides:

> If such an action is brought before the expiration of [45 days after the date that the paragraph IV notice is received], the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

> **(I)** if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--
> **(aa)** the date on which the court enters judgment reflecting the decision; or
> **(bb)** the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

Merck argues that the parenthetical clause of § 355(j)(5)(B)(iii)(I), "(including any substantive determination that there is no cause of action for patent infringement or invalidity)," instructs that a dismissal for lack of subject matter jurisdiction would lift the 30-month stay on an ANDA. Apotex contends that the FDA has not yet construed the provision, and that the FDA's construction of similar, previously disputed language suggests that nothing less than a court decision of invalidity, noninfringement or unenforceability would affect the stay.[6] Neither the parties nor the court can be certain of how the provision will be applied to Apotex. Moreover, the matters pending before the court do not mandate this court's interpretation of the statute. It is noteworthy, however, that the FDA considered a precise answer, by way of a proposed rule, but later withdrew it without comment. The FDA's proposed rule § 314.107(g) provided in pertinent part:

> *Effect of dismissal of litigation on 30-month stay.* If the patent litigation between the ANDA applicant and the patent owner or NDA holder described in paragraph (b)(3)(A) of this section is dismissed without a court decision on the merits of the patent claim, whether the dismissal is with or without prejudice, the agency may immediately approve the ANDA that was the subject of the litigation, if it is otherwise eligible for approval.

[6] *See Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.D.C. 2006) (upholding FDA's decision finding that dismissal for lack of subject matter jurisdiction did not qualify as a "court decision" sufficient to trigger the 180-day exclusivity period).

180-Day Generic Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42886 (1999) (to be codified at 21 C.F.R. pt. 314) (proposed Aug. 6, 1999), withdrawal of proposed rule reflected in 67 Fed. Reg. 66593 (2002).

Certainly, if the mere filing of a patent infringement suit can result in an irrevocable 30-month stay on an ANDA application, except in the limited circumstances of a "substantive decision" on the merits or other narrower circumstances where a court may shorten the stay, then Apotex has a legitimate concern about how such a policy is susceptible to abuse by pioneer drug companies. Ultimately, however, the court cannot remedy every harm or prejudice a party endures. Moreover, not every business disadvantage is appropriately deemed legal injury. The fiercely competitive pharmaceutical industry does not escape these realities. The existing law does not provide an absolute right of a generic drug company to enter the market in which a pioneer drug company and a first-filing generic applicant have legally achieved some market exclusivity.

The court understands that Apotex is at a competitive disadvantage, but as to the harm it claims to have endured, and the relief it seeks, the court's hands are tied. In *Teva v. Pfizer*, the Federal Circuit stated:

> The fact that Teva is disadvantaged from a business standpoint by Ivax's 180-day exclusivity period and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. It is not the product of a threat of suit by Pfizer.

395 F.3d 1324, 1338 (Fed. Cir. 2005), *abrogated by MedImmune v. Genentech*, 127 S. Ct. 764 (2007). Notwithstanding the Supreme Court's abrogation of the Federal Circuit's reasonable

apprehension test, the Federal Circuit's analysis of the distinction between a business disadvantage and an Article III controversy applies with equal force to Apotex's opposition to Merck's motion to dismiss, as well as its motion to add an antitrust counterclaim on the same grounds.

Apotex attempts to distinguish its case from *Teva v. Pfizer* by emphasizing that, unlike Pfizer, Merck chose to sue Apotex, knowing there was no infringement, and then covenanted not to sue. The court will not engage in fact finding as to the disputed accounts of what Merck knew about the merits of an infringement claim against Apotex at the time it filed suit, and whether and under what circumstances, Merck attempted to glean further information before filing suit. The court does not need to resolve these issues because the mere filing of a paragraph IV certification in an ANDA constitutes infringement. *See* 35 U.S.C. § 271(e)(2)(A). Accordingly, Apotex's filing of its ANDA on Merck's Fosamax drug was an act of infringement that afforded Merck the right to sue. The statutory provisions that allow suit under these circumstances render the patentee's subjective motivations for filing suit irrelevant.[7]

Intellectual property law and principles foster the creation of market power and antitrust law and principles respond to market power abuses, however, both systems operate to advance consumer welfare by allocating resources, cultivating innovation, and promoting technological progress. *See, e.g.*, Lawrence A. Sullivan & Warren S. Grimes, *The Law of Antitrust: An Integrated Handbook*, (West Group 2000), §§ 15.1 at 800-801. A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market." *See*

[7] The court is by no means discharging the requirements of Rule 11 in the context of Hatch Waxman litigation. In this case, however, there are no alleged facts from which the court can conclude that, in fact, Merck knew that Apotex's generic version of Fosamax did not infringe Merck's patents at the time it filed suit pursuant to its statutory right to do so upon Apotex's paragraph IV certification. Although the Rule 12(b)(6) standard requires the court to accept all well-pleaded allegations as true, and to view them in the light most favorable to plaintiff, the court will not credit bald and conclusory allegations. *See United States v. Vespe*, 868 F.2d 1328, 1340 (3d Cir. 1989) (stating conclusory statements need not be credited).

*Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.,* 324 U.S. 806, 816 (1945). Thus, "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present." *Schering-Plough v. Federal Trade Comm'n,* 402 F.3d 1056, 1065-1066 (11th Cir. 2005). When patentees attempt to extend their legal monopoly beyond that which is permitted by their statutory grants, such actions can trigger antitrust liability. *Andrx Pharms., Inc. v. Biovail Corp. Intern.*, 256 F.3d 799, 813 (D.C. Cir. 2001) ("[E]ven a patent-right holder is not immune from antitrust liability.").

Any adverse effects within the scope of a patent or statutory right to exclude, however, cannot be redressed by antitrust law. *See United States v. Studiengesellschaft Kohle, m.b.H.,* 670 F.2d 1122, 1127 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent *and is otherwise legal.*") (emphasis added). The existing body of case law involving antitrust allegations in the context of ANDA litigation tends to fall within two categories: cases in which the parties bilaterally entered into a collusive agreement that exceeded the scope of a patent grant, thus warranting antitrust scrutiny,[8] and cases in which the patentee was considered to have lawfully enforced its patent right, albeit with the consequence of delaying or inhibiting competition. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) and *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (involving agreements among innovator and generic drug companies that incurred antitrust liability).

[8] "It is widely understood that the 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a 'non-entry' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely." Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes,* 87 Minn. L.Rev. 1719, 1755 (2003).

The futility of Apotex's proposed amendment is further demonstrated by previously unsuccessful efforts to attach antitrust liability to pharmaceutical companies acting within the Hatch-Waxman regulatory framework and patent grant. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 524 (E.D.N.Y. 2005) (holding that conduct within the scope of the patent grant is exempt from antitrust scrutiny); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) (affirming district court decision, which held that the claimed injury was not "antitrust injury," which must be caused by something other than the regulatory action limiting entry to the market); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 23-25 (D. Mass. 2000) (dismissing an antitrust counterclaim of second ANDA filer against pioneer drug company because the counterclaimant failed to show antitrust injury where the statutory scheme, and not the pioneer drug company, prevented it from entering the market).

Thus, Merck's challenged conduct—filing suit upon notice of Apotex's paragraph IV certification and covenanting not to sue—are expressly sanctioned by the Hatch-Waxman Amendments or contemplated by its legislative history. Likewise, the consequences to Apotex—delayed entry in the market for alendronate sodium tablets—are specific products of the statute. Having failed to establish antitrust injury and causal connection between Merck's legal actions and Apotex's alleged harm, which are necessary requirements for antitrust standing, the court considers Apotex's requested amendment to be futile.

## VI. CONCLUSION

Accordingly, Merck's motion to dismiss (D.I. 15) is granted as Apotex has failed to establish the existence of an actual case or controversy under the current state of the law. The Clerk of the Court shall mark this action closed and all other pending motions are denied.

Dated: May 21, 2007

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

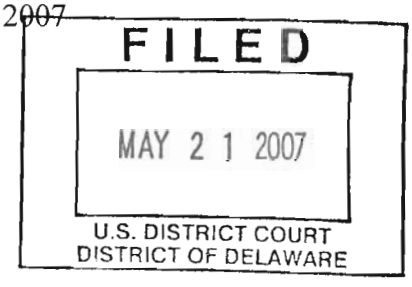
| | | |
|---|---|---|
| MERCK & CO., INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | C.A. No. 06-230 (GMS) |
| APOTEX, INC., | ) | |
| Defendant. | ) | |

**ORDER**

IT IS HEREBY ORDERED that:

1. Merck's motion to dismiss for lack of subject matter jurisdiction (D.I. 15) is GRANTED.
2. Apotex's motion for leave to file a surreply (D.I. 26) is DENIED.
3. Apotex's motion for leave to file its first amended answer, affirmative defenses, and counterclaims (D.I. 28) is DENIED.
4. Apotex's motion for leave to substitute corrected exhibits to its pending motion for leave (D.I. 36) is DENIED as moot.
5. Merck's motion to stay (D.I. 68) is DENIED as moot.
6. All claims in Merck's Complaint (D.I. 1) are DISMISSED.
7. All counterclaims in Apotex's Answer, Affirmative Defenses, and Counterclaims (D.I. 8) are DISMISSED.
8. Each party shall bear its own costs and attorneys' fees.

Dated: May 21, 2007




UNITED STATES DISTRICT JUDGE